

## **REMARKS**

This Amendment is responsive to the Office Action of May 12, 2010, which reversed the prior allowance of Claims 7 and 28, objected to the Abstract for exceeding 150 words, objected to the specification for including reference numbers not shown in the drawings, and and objected to the drawings for not showing item numbers referenced in the text. Applicant has carefully addressed each concern below.

### **Abstract**

Applicant has amended the Abstract to reduce the word count from 170 words to 136 words. Applicant respectfully submits that its abstract is now in compliance with 37 CFR 1.72.

### **Specification**

Applicant has amended paragraph [0072] to explicitly associate the "proximal tang" and "distal tang" in the original specification with reference numbers 56 and 58 shown in original Figure 15. Applicant has also amended the reference number for the "short portion" from 44 to 44c in conformance with applicant's original intent of referencing elements of similar structure with the same reference number used previously, followed by the lower case letter "c." Applicant thanks the Examiner for noting these minor disconnects between paragraph [0072] of the specification and Figure 15.

### **Drawings**

Applicant has amended Figures 11, 12, 13, 14, 15, and 16B, attaching "Replacement Sheets" and "Sheets Showing Changes Made" relative to corresponding

sheets 3/12 and 4/12. In particular, Applicant amended Figure 11 to include reference 20b, Figure 12 to include reference 20b, Figure 13 to include references 20b and 42, Figure 14 to include references 20b and 38b, Figure 15 to include references 20c and 28c, and Figure 16B to include reference 60.

The Examiner is thanked for noting these discrepancies and is invited to telephone the undersigned attorney if any further omission of this nature become evident.

### **Claims 7 and 28**

On May 6, 2009, Applicant replaced independent Claim 1 with new independent Claim 28, and also amended Claim 7 to depend from new Claim 28. In pages 7-13 of its remarks, Applicant explained how new Claim 28 is allowable over Toy in view of Trott.

On July 31, 2009, the Office Action allowed Claims 28 and 7, but rejected certain other claims.

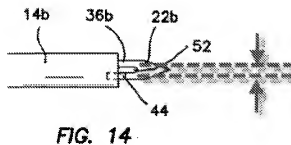
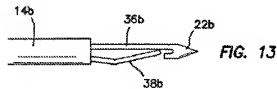
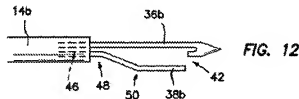
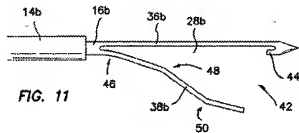
On February 1, 2010, applicant amended the application to take a patent on the allowed claims 28 and 7. Now, however, the Office Action of May 12, 2010 reverses the prior indication of allowance based, it appears, Figure 4 of Toy. Applicant respectfully traverses.

In particular, Claim 28 recites bifurcated portions that are not fairly taught or suggested by Toy (emphasis added):

bifurcated portions of the needle assembly defining a suture slot with a proximal end and a distal end, the bifurcated portions including a backing arm and a gathering arm that are integral with one another at the proximal end of the suture slot, **the backing arm and gathering arm having a proximate but spaced relationship when the needle assembly is in the retracted state**

and having a separated and further spaced relationship when the needle assembly is in the extended state, the backing arm and gathering arm being biased to the separated relationship;

As discussed at pages 8-9 of Applicant's 5/6/09 response, Claim 28 defines "bifurcated portions" that uniquely have a proximate but spaced relationship when the needle assembly is in the extended state (Figure 11), and when the needle assembly is in the retracted state (Figure 14) (emphasized below by the by the dashed lines and arrows):



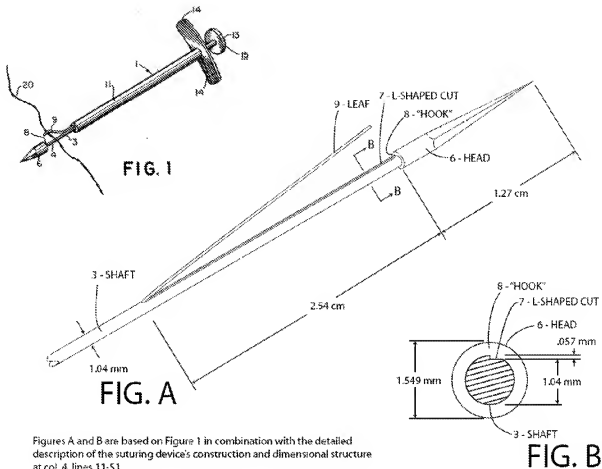
The Office Action, at page 5, lines 10-14, asserts that Toy et al. teach the bolded element first shown above. In fact, at lines 17-20, the Office Action specifically contends that:

the small clearance between the inner diameter of sheath  
(11) and shaft (3) will allow the gathering arm (9) to extend[]  
outward away from the backing arm (7) when the needle  
assembly is in retracted position, thereby forming a suture  
slot...

Applicant respectfully traverses because Toy et al. explicitly teach that their goal is to have the leaf or "latch" 9 actually "clamp" down onto the suture (Col. 5, lines 31-34), the exact opposite of a proximate but spaced relationship:

spaced location on the other side of the incision from the  
puncture point 131. When the distal end of the suture passer  
1 is in the cavity 122, the hook 8 of the suture passer 1 is  
manipulated to capture the free end 24 of the suture 20 and  
the latch 9 is operated to clamp onto the body of the suture  
20 at a position adjacent the leading part 24. The pointed  
head 6 is then withdrawn from the tissue 126 at the puncture

Using the actual dimensions provided by Toy et al. themselves, at col. 4, lines 11-51, the undersigned attorney created the following "FIG. A" and "FIG. B" (first presented on 5/6/09) in order to accurately show the length and thickness of the leaf 9, and L-shaped cut 7 used to create the leaf 9, relative to the diameter of the shaft 3 and the head 6:



Figures A and B are based on Figure 1 in combination with the detailed description of the suturing device's construction and dimensional structure at col. 4, lines 11-51

One can see that the Toy et al. device will, as required by their written disclosure, “clamp” on the suture when the leaf 9 and the shaft 3 are retracted into the sheath 11. This is consistent with Toy et al.’s disclosure that the OD of the needle shaft 3 is 1.04 mm (col. 3, line 37) and the ID of the sheath 11 is 1.194 mm (col. 3, line 54), a difference of only .154 mm.

Of further significance, as the needle assembly is partially retracted through the intermediate partially retracted positions shown in Figures 12 and 13 above, the bends 48 and 50 in the “gathering arm” 38b cause the gathering arm contact the backing arm 36b “while still maintaining the passage 42 for the suture” (emphasis added), i.e. to gather in the suture without clamping it:

**[0070]** In Figure 13, the needle assembly 20b is even further retracted. This has caused the bend 48 to straighten bringing the gathering arm 38b into contact with the backing arm 36b **while still maintaining the passage 42 for the suture.**

In light of this disclosure, Applicant has amended Claim 28 to further clarify the structural relationship created by the bends in its gathering arm as follows:

bends in the gathering arm causing the distal end of the gathering arm to extend away from the backing arm to define a wide passage into the suture slot when the needle assembly is in the extended state and the backing arm and gathering arm have the separated relationship, causing the distal end of the gathering arm to extend toward and contact the backing arm while still maintaining a passage for the suture proximal of where the distal end of the gathering arm contacts the backing arm in order to gather the suture with the passage when the needle assembly is in a partially retracted position, and causing the distal end of the gathering arm to substantially align with the small portion extending from the sharp needle tip when the needle assembly is in the retracted state.

Toy et al. focus on a clamping action and do not, therefore, teach or suggest bends for “causing the distal end of the gathering arm to extend toward and contact the backing arm while still maintaining a passage for the suture proximal of where the distal end of the gathering arm contacts the backing arm in order to gather the suture with the passage when the needle assembly is in a partially retracted position.” In fact, within its detailed description, Toy et al. reference only a single bend, namely the bend that causes latch 9 to open away from the needle shaft 3 (see col. 4, 47-49).

### Summary

Based on the attached amendments and accompanying remarks, Applicant respectfully submits that the pending Claims 28 and 7 are in patentable condition and earnestly solicits a Notice of Allowance. Applicant encourages the Examiner to telephone the undersigned attorney if it appears that a telephone conference would further this case in any way.

Respectfully submitted,

/sca/ - signed 11/12/2010

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